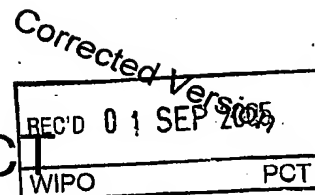


PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2005/001179

International filing date (day/month/year)
24.03.2005

Priority date (day/month/year)
26.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61F2/44, A61F2/46

Applicant
PEARSALLS LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Buchmann, G

Telephone No. +49 89 2399-2288



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/001179

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/001179

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 25-30

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 25-30

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/001179

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9,24
	No: Claims	1-8,10-23
Inventive step (IS)	Yes: Claims	9,24
	No: Claims	1-8,10-23
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	-

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Claims 25-30 of the present application define a surgical technique including the removal of a part of a spinal disc. This technique represents a method for surgical treatment of the human body in the sense of Rule 67.1 (iv) PCT. Therefore, no examination is carried out for these claims according to Art. 34 (4)(a)(I) PCT.

Re Item V.

- 1 Reference is made to the following document:

D1 : WO 92/10982 A (PFIZER HOSPITAL PRODUCTS GROUP, INC) 9 July 1992
(1992-07-09)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (see page 21, lines 8-11):

A spinal implant including a porous component (102) and one or more filling elements (100) provided within the porous component.

Therefore, the subject-matter of claim 1 is already known from document D1.

3 DEPENDENT CLAIMS 2-8, 10-23

Dependent claims 2-8, 10-23 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

See the documents cited in the international search report and the corresponding passages.

4 DEPENDENT CLAIMS 9, 24

The combination of the features of dependent claims 9, 24 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:
Document D1 is regarded as representing the closest prior art (see above).

The spinal implant as defined in claim 9 or claim 24 differs from the prior art in that the porous component or the filling elements are restrained by a bioabsorbable material in a first state, the absorption of the material allowing the transition into a second state.

The problem to be solved may be regarded as to provide a spinal implant wherein at an early stage, functions are performed by the implant, and at a later stage, these functions can be taken over by newly grown tissue.

The solution as defined in the present claims 9 and 24 is neither disclosed nor fairly suggested by any of the documents cited in the search report.

Re Item VII.

The independent claims are not written in the two part form (Rule 6.3(b) PCT), which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 6.2(b) PCT). This applies to both the preamble and characterising portion (see the PCT Guidelines, III-4.11).

The document D1 is not identified in the description and the relevant background art disclosed therein is not discussed (Rule 5.1(a)(ii) PCT).

Re Item VIII.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2005/001179

The present claims 6, 8, 14, 22, 23 lack clarity in the sense of Art. 6 PCT for the following reasons:

Claim 6: Claim 6 defines a material to be "intended to promote tissue ingrowth". This does not represent a technical feature of the material, because the intention of the applicant is not a part of the implant.

Claim 8: Claim 8 defines how the bio-absorbable material is used. The use of a material, however, is no technical feature of the material.

Claim 14: As the features after the term "for instance" are merely optional, claim 14 only defines an implant comprising one or more filling elements, which is already defined in claim 1.

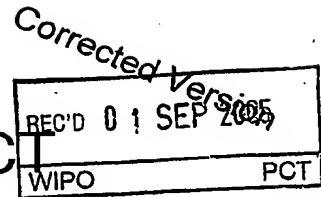
Claim 22: See claim 6.

Claim 23: See claim 8.

Furthermore, the references to previous claims appear to be incorrect for the following dependent claims: 8, 9, 20, 21, 24.

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FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2005/001179

International filing date (day/month/year)
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Priority date (day/month/year)
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International Patent Classification (IPC) or both national classification and IPC
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Applicant
PEARSALLS LIMITED

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- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
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- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

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For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/001179

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
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2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
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 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
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 - ☐ filed together with the international application in computer readable form.
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/001179

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 25-30

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 25-30
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/001179

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9,24
	No: Claims	1-8,10-23
Inventive step (IS)	Yes: Claims	9,24
	No: Claims	1-8,10-23
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	-

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

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see separate sheet

Re Item III.

Claims 25-30 of the present application define a surgical technique including the removal of a part of a spinal disc. This technique represents a method for surgical treatment of the human body in the sense of Rule 67.1 (iv) PCT. Therefore, no examination is carried out for these claims according to Art. 34 (4)(a)(I) PCT.

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2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

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Therefore, the subject-matter of claim 1 is already known from document D1.

3 DEPENDENT CLAIMS 2-8, 10-23

Dependent claims 2-8, 10-23 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

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4 DEPENDENT CLAIMS 9, 24

The combination of the features of dependent claims 9, 24 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:
Document D1 is regarded as representing the closest prior art (see above).

The spinal implant as defined in claim 9 or claim 24 differs from the prior art in that the porous component or the filling elements are restrained by a bioabsorbable material in a first state, the absorption of the material allowing the transition into a second state.

The problem to be solved may be regarded as to provide a spinal implant wherein at an early stage, functions are performed by the implant, and at a later stage, these functions can be taken over by newly grown tissue.

The solution as defined in the present claims 9 and 24 is neither disclosed nor fairly suggested by any of the documents cited in the search report.

Re Item VII.

The independent claims are not written in the two part form (Rule 6.3(b) PCT), which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

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INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2005/001179

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- Claim 6: Claim 6 defines a material to be "intended to promote tissue ingrowth". This does not represent a technical feature of the material, because the intention of the applicant is not a part of the implant.
- Claim 8: Claim 8 defines how the bio-absorbable material is used. The use of a material, however, is no technical feature of the material.
- Claim 14: As the features after the term "for instance" are merely optional, claim 14 only defines an implant comprising one or more filling elements, which is already defined in claim 1.
- Claim 22: See claim 6.
- Claim 23: See claim 8.

Furthermore, the references to previous claims appear to incorrect for the following dependent claims: 8, 9, 20, 21, 24.